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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,006	06/29/2001	Gregory T. Bleck	GALA-06415	1148

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EXAMINER

MARVICH, MARIA

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 04/23/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/897,006

Applicant(s)

BLECK, GREGORY T.

Examiner

Maria B Marvich, PhD

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 and 30-33 is/are pending in the application.
- 4a) Of the above claim(s) 1-20 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 and 31-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

This office action is in response to an amendment filed 4/3/03. Claims 1-28 and 30-33 are pending. Claim 29 is canceled. Claims 1-20 and 30 are withdrawn from consideration.

Election/Restrictions

Applicant's election without traverse of Group IV in Paper No. 13 is acknowledged. Claim 29 has been canceled. Claims 1-20 and 30 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Information Disclosure Statement

Copies of references labeled on the IDS as reference #90 and #141 were not found in the IDS submitted 3/13/03, paper # 11. Copies of the articles not found in the parent case were not considered. Should applicant want these considered please include them in a reply to this office action. Reference # 177, Antibodies, A Laboratory Manual by Harlow and Lane, was not considered. The pages submitted with the IDS consisted of the cover, inside page and copyright page, which pages were not indicated on the IDS. Applicant should indicate the pages of the Laboratory manual to be considered and should submit the appropriate pages.

Double Patenting

Claim 32 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 26. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim

Art Unit: 1636

to object to the other as being a substantial duplicate of the allowed claim. See MPEP

§ 706.03(k).

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 21 and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Dirks et al. (US patent 6,060,273).

Dirks et al teach a method for the production of proteins composed of one or more polypeptides or subunits such as immunoglobulins (column 8, line 59-65 and claims 7 and 9). Vectors were used in the method that contain multicistronic expression unit characterized by the general formula p-5'UTR-C1- (IRES-Y-Cam2)n-3'UTR-polyA (claim 1) and provide for the equimolar expression of polypeptides or subunits (column 5, line 22-35). An exemplified ratio of C1 to C2 is 1:1 which absent evidence to the contrary is about 0.9:1 (column 5, line 22-35).

Claims 21-24, 26 and 31-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Piechaczyk et al. (US application 2002/0168339).

Piechaczyk et al teach methods for the production of Tg10 antibody using pLXPXSN a retroviral vector in which the heavy and light chains of the immunoglobulin are expressed from either side of an IRES and this vector is called PM130 [0070]. PM130 was used to express a functional Tg10 antibody (table 1). Absent evidence to the contrary, the subunits are expressed

Art Unit: 1636

in about a 0.9:1.1 ratio as equimolar ratios of the heavy and light chains are required for immunoglobulin assembly and the product of the PM130 is a functional TG10 antibody.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-25 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dirks et al. (US patent 6,060,273) in view of Voet and Voet, Biochemistry (1990) pp 1099-1100.

Applicant claims a method for the production of an immunoglobulin comprising a vector comprised of a first and second immunoglobulin gene separated by an IRES. The immunoglobulin genes can be heavy ($\alpha, \mu, \delta, \epsilon, \gamma$) or light (κ, λ) and are secretory immunoglobulins.

Dirks et al teach a method for the production of proteins composed of one or more polypeptides or subunits such as immunoglobulins (column 8, line 59-65 and claims 7 and 9). Vectors were used in the method that contain multicistronic expression unit characterized by the general formula p-5'UTR-C1- (IRES-Y-Cam2)n-3'UTR-polyA (claim 1) and provide for the equimolar expression of polypeptides or subunits (column 5, line 22-35). An exemplified ratio of C1 to C2 is 1:1 which absent evidence to the contrary is about 0.9:1 (column 5, line 22-35). Dirks et al. do not teach that the immunoglobulin is a secretory immunoglobulin and that it is

Art Unit: 1636

made by expression of a light and heavy chain and that these light and heavy chains are selected from a group consisting of κ and λ and $\alpha, \mu, \delta, \epsilon$ and γ respectively.

Voet and Voet teach that immunoglobulins include IgA, which is a secretory immunoglobulin. Voet and Voet also teach that immunoglobulins consist of 2 heavy chains designated as $\alpha, \mu, \delta, \epsilon, \gamma$ and 2 light chains designated as κ or λ (pp 1099–1100).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the teachings of Dirks et al. such that the immunoglobulin coding sequences to be used in the multicistronic expression unit be comprised of a light and a heavy chain comprised of κ and λ or $\alpha, \mu, \delta, \epsilon$ and γ respectively of any immunoglobulin such as IgA. A multicistronic expression unit containing a heavy and light chain coding sequence separated by an IRES would then be used to express an immunoglobulin molecule. A person of ordinary skill in the art would have been motivated to use the heavy chains $\alpha, \mu, \delta, \epsilon, \gamma$ and the light chains κ or λ as subunits in the expression cassette of Dirks et al. as an immunoglobulin is comprised of two heavy and two light chains and therefore a cassette encoding for each is necessary for the production of a functional immunoglobulin. The heavy chains would necessarily be chosen from the group $\alpha, \mu, \delta, \epsilon$ and γ and the light chains from the group κ and λ as these are the only identified heavy and light chains of an immunoglobulin protein. Given the teachings of the cited art and the level of skill of the ordinary skilled artisan at the time of the applicant's invention, it must be considered that said ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 21 and by dependency claims 22-28, 31-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 recites the limitation "said antibody" in 21. There is insufficient antecedent basis for this limitation in the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-28 and 31-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicant's claims read on a first and second exogenous gene that encodes a first and second immunoglobulin chain. The claim therefore reads on a genus claim encompassing any immunoglobulin gene from any species. The written description requirement for a genus claim may be satisfied through sufficient description of a relevant representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics such as structure or other physical and/or chemical properties, by functional characteristics coupled with

Art Unit: 1636

a known or disclosed correlation between function and structure or by a combination of such identifying characteristics sufficient to show applicants were in possession of the claimed genus.

In the instant case, applicants teach the production of MN14, LL2, and botulinum toxin immunoglobulin heavy and light chains. The genomic version of any of the recited genes is not disclosed by the specification nor does the prior art apparently disclose the entire gene. While the cDNAs may be known, not all of the genes have been characterized. Because all of the components of the gene such as regulation sequences, introns, and exons must be determined empirically in order to generate the immunoglobulin genes, applicant claims the gene without any disclosure about its structure. The skilled artisan would not conclude that applicant was in possession of viral vector comprising the claimed genes.

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (703) 605-1207. The examiner can normally be reached on M-F (6:30-3:00).

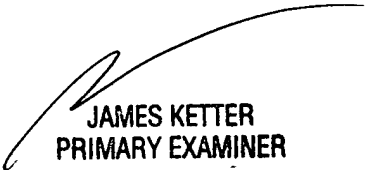
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-4242 for After Final communications.

Art Unit: 1636

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3291.

Maria B Marvich, PhD
Examiner
Art Unit 1636

April 21, 2003



JAMES KETTER
PRIMARY EXAMINER